

Applicants: Gary A. Beaudry and Paul J. Maddon
Serial No.: 08/485,163
Filed June 7, 1995
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REMARKS

Claims 47-55 are pending in the subject application. By this Amendment, applicants have amended claims 47, 48 and 49. Applicants note that certain of the amendments to claim 47 involve merely formatting changes to correct the spelling of "heterotetramer" and to replace the word "said" with "the". Applicants note that the other claim amendments are fully supported in the specification at, *inter alia*, the following passages: Claim 47: page 27, line 25 to page 28, line 29; and Claims 48 and 49: page 21, lines 10-20; page 46, lines 3-15; and page 49, lines 10-12. Thus, applicants maintain that these amendments do not raise any issue of new matter.

Applicants have also amended the title of the application to reflect the subject matter of the claimed invention, and amended the specification to identify trademarked products. Applicants maintain that these amendments also raise no issue of new matter. Accordingly, applicants respectfully request that the Examiner enter this Amendment. Upon entry of this Amendment, claims 47-55, as amended, will be pending and under examination.

The Invention

The invention claimed in the subject application is directed to a transformed host cell comprising at least two vectors, one vector comprising a DNA sequence encoding heavy chains of a CD4-IgG2 chimeric heterotetramer, and one vector comprising a DNA sequence encoding light chains of the CD4-IgG2 chimeric heterotetramer. The CD4-IgG2 chimeric heterotetramer comprises two heavy chains having the amino acid sequence set forth in SEQ ID NO:4, and two light chains having the amino acid sequence set forth in SEQ ID NO: 6, and is capable of neutralizing an HIV-1-infected individual's HIV-1 virus.

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Objections to the Specification

Title

The Examiner stated that the title of the invention is not descriptive. The Examiner also stated that a new title is required that is clearly indicative of the invention to which the claims are directed.

In response, applicants have amended the title as set forth above to reflect the subject matter of the claimed invention. Accordingly, applicants respectfully request that this ground of objection be withdrawn.

References to Trademarks

The Examiner stated that the application is required to be reviewed and all spelling, trademarks, and like errors corrected. The Examiner further stated that trademarks should be capitalized or accompanied by the ™ or ® symbol wherever they appear and be accompanied by the generic terminology. The Examiner also noted that although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

In response, applicants have amended the specification as set forth above to identify trademarks by the ® symbol. Applicants have also taken the opportunity to correct obvious typographical and grammatical errors as indicated. Applicants therefore respectfully request that this ground of objection be withdrawn.

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Errors in scanned specification

The Examiner stated that the subject specification that has been scanned into Image File Wrapper (IFW) has numerous errors including the omission of letters and words (citing, e.g., the entire specification, including page 4, lines 1-2; page 21, lines 1-2; page 22, lines 1-2, etc.). The Examiner also stated that a substitute specification is required because numerous entries would be needed to amend the specification to account for all of the missing letters and words in the current scanned specification.

The Examiner further stated that the substitute specification filed must be accompanied by a statement that it contains no new matter, and that such statement must be a verified statement if made by a person not registered to practice before the Office.

In response, applicants attach hereto as **Exhibit A** a copy of the complete application, including specification and original claims. The undersigned affirms that the attached copy of the application, containing a substitute specification, is a photocopy of the application as filed and thus contains no new matter.

Priority claims

The Examiner also stated that applicants should update the status of the priority documents on the first line of the specification.

In response, applicants have amended the first paragraph of the specification as indicated above to update the status of the priority documents.

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Rejections under 35 U.S.C. §112, first paragraph

The Examiner rejected claims 47-55 under 35 U.S.C. §112, first paragraph, as allegedly not containing a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed. The Examiner stated that the specification as originally filed does not provide support for the following elements recited in the claims:

"at least one vector" - recited in claim 47, lines 2 and 4;
"mammalian cell" - recited in claim 48; and
"COS cell, a CHO cell or a myeloma cell" - recited in claim 49.

The Examiner noted that applicants' Amendment, filed June 3, 2002, states that support for the written description of the above claim elements may be found at pages 12 and 27-29 for claim 47, and page 21 for claims 48-49. The Examiner asserted that the specification as filed does not, however, appear to provide sufficient written description for the generic recitation of the claimed "at least one vector", "mammalian cell", and "COS cell, a CHO cell or a myeloma cell". In this regard, the Examiner stated that there does not appear to be a written description of "at least one vector", including "at least one vector" in the context of the claimed transformed host cells. The Examiner also stated that whereas the specification provides for specific examples of mammalian cell lines, including specific COS, CHO and myeloma cell lines, there appears to be insufficient written description for the genus comprising cells, COS cells, CHO cells and myeloma cells, as currently encompassed by the claimed invention.

The Examiner further stated that the claims represent a departure from the specification and claims as originally filed,

and applicants' reliance on generic disclosure and possibly certain limited species does not provide sufficient direction and guidance to broadly claim generic "limitations" as currently recited. The Examiner also stated that the instant claims are drawn to new matter since they broadly recite different genres which are not disclosed in the original application as filed, which discloses certain specific vectors as well as numbers of vectors (versus "at least one") and certain cell lines (versus "cells") (citing *In re East and Harmon* 181 U.S.P.Q. 716 (C.C.P.A., May 9, 1974); and M.P.E.P. §2163.05 (I)).

The Examiner also stated that the specification does not provide sufficient blazemarks or direction for broadly claiming "at least one vector" and "cells", as currently recited. The Examiner asserted that the instant claims now recite elements which were not clearly disclosed in the specification as filed and now change the scope of the disclosure as filed. The Examiner further stated that such limitations recited in the present claims, which did not appear in the specification as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. §112.

The Examiner requested that applicants cancel the new matter in the response to the Office Action, or alternatively, provide sufficient written support for the elements indicated above (citing M.P.E.P. §714.02 and §2163.06).

In response, applicants respectfully traverse this rejection. Without conceding the correctness of the Examiner's position, applicants note that claim 47, as amended, does not recite the phrase "at least one vector." Similarly, applicants note that claim 48 does not recite the phrase "mammalian cell". Thus, applicants maintain that the rejections based on the presence of these phrases in the claims are moot.

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Applicants note that claim 49, as amended, refers to "a COS cell, a CHO cell or a myeloma cell". However, claim 49, as amended, makes it clear that COS, CHO and myeloma cells are cells in mammalian cell lines. Applicants respectfully direct the Examiner's attention to the specification at, *inter alia*, page 21, lines 10-20; page 46, lines 3-15; and page 49, lines 10-12, which indicates that these mammalian cell-line cells are appropriate host cells for expressing the CD4-IgG2 heterotetramer. Thus, applicants maintain that claim 49, as amended, does not recite any element which is not clearly disclosed in the specification as filed.

Applicants note that each of claims 50-55 depends from claim 47 and therefore necessarily possesses all the elements of claim 47. Moreover, applicants maintain that none of claims 50-55 possesses any element that is not fully supported in the specification as filed. Accordingly, applicants maintain that claims 47-55, as amended herein, satisfy the written description requirement of 35 U.S.C. §112, first paragraph. Applicants respectfully request, therefore, that the Examiner reconsider and withdraw this ground of rejection.

In view of the remarks made above, applicants respectfully request that the Examiner reconsider and withdraw the objections to the specification and claim rejections set forth in the April 15, 2005 Office Action, and earnestly solicit allowance of all claims pending in the subject application.

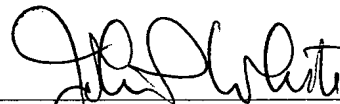
If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

Pursuant to 37 C.F.R. 1.136(a) and 37 C.F.R. 1.17 (a)(3), a fee of FIVE HUNDRED AND TEN DOLLARS (\$510.00) is required for a

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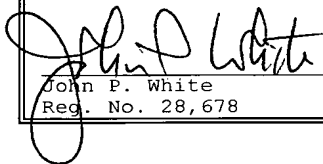
three-month extension of time for responding to the April 15, 2005 Office Action, and a check for this amount is enclosed. No other fee is believed to be required for filing this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:
Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



10/17/05

John P. White	Date
Reg. No. 28,678	